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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/785,266	02/24/2004	Douglas A. Collins	07959.105030 (COP 1003 CO	3875
20786	7590 02/23/2005	EXAMINER		INER
KING & SPALDING LLP			JONES, DAMERON LEVEST	
191 PEACHT	TREE STREET, N.E.			
ATLANTA,	GA 30303-1763		ART UNIT	PAPER NUMBER
•	·		1616	· <del>-</del>

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
Office Action Summary		10/785,266	COLLINS ET AL.			
		Examiner	Art Unit			
		D. L. Jones	1616			
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SH THE - Exte after - If the - If NO - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. e period for reply specified above is less than thirty (30) days, a reply of period for reply is specified above, the maximum statutory period we are to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be timed within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONET	nely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133).			
Status						
1)⊠	1) Responsive to communication(s) filed on <u>5/10/04; 11/26/04; and 2/24/04</u> .					
2a)□	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.					
3)□	☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Dispositi	ion of Claims					
5)□ 6)⊠ 7)□	<ul> <li>4)  Claim(s) 1,4-11,20-27,33-44 and 47-62 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1,4-11,20-27,33-44 and 47-62 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>					
Applicati	ion Papers					
9) The specification is objected to by the Examiner.						
10)	10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
440	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority (	ınder 35 U.S.C. § 119					
a)l	Acknowledgment is made of a claim for foreign  All b) Some * c) None of:  1. Certified copies of the priority documents  2. Certified copies of the priority documents  3. Copies of the certified copies of the priorical application from the International Bureausee the attached detailed Office action for a list of	s have been received. s have been received in Application ity documents have been receive I (PCT Rule 17.2(a)).	on No ed in this National Stage			
Attachmen	t(s)					
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)						
3) 🛛 Inforr	e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date <u>5/10/04</u> .	Paper No(s)/Mail Da				

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## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the following:

(a). the amendment filed 2/24/04 wherein the specification was amended; claims

56 and 60 were amended; and claims 63-69 were canceled; and

(b). the amendment filed 11/26/04 wherein claims 2, 3, 12-19, 28-32, 45, 46, and

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63-69 are canceled and claims 1, 47-49, and 60 are amended.

**Note**: Claims 1, 4-11, 20-27, 33-44, and 47-62 are pending.

## **APPLICANT'S INVENTION**

2. Applicant's invention is directed to compounds as set forth in independent claims 1 and 33 and uses thereof.

## **RESPONSE TO APPLICANT'S ELECTION**

3. Applicant's election of the species of claim 1 wherein the peptide residue is poly-L-lysine (8 units); the non-metallic radionuclide is fluorine-18; and X=CN filed 11/26/04 is acknowledged.

**Note**: Initially, Applicant's elected species was searched. However, since no prior art was found which could be used to reject Applicant's claims, the search was extended over the full scope of the invention.

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# **DOUBLE PATENTING REJECTIONS**

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 4-11, 20-27, 33-44, and 47-62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 15, 16, 19, 21, 23-26, 28-31, and 34-41 of U.S. Patent No. 6,838,073. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compounds of formula I that is linked to one or more peptide residues or amino acid residues. The claims differ in that in the instant

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invention, the central atom is cobalt and that of the patented invention is copper. It would be obvious to replace the copper with cobalt because claim 15 of the patented invention disclose that the radioisotope may be selected from cobalt or copper in addition to other isotopes. In addition, while patented invention is directed to one or more metallic radionuclides, it would be obvious to use one or more non-metallic radionuclides as set forth in the instant invention because claim 25, for example, in the patented invention is directed to the detectable radionuclide being non-metallic.

#### 112 REJECTIONS

- 6. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 7. Claims 26, 27, and 33-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

<u>Claims 26 and 27</u>: The claim as written is ambiguous because there are too many attachments to the carbon atom (see the [CH2] group). Thus, since claim 26 is unclear the claims depending thereof, claims 27, is also ambiguous

<u>Claims 33-36</u>: The claim as written is ambiguous because there are too many attachments to the carbon atom (see the [CH2] group). Thus, since independent claim 33 is unclear the claims depending thereof, claims 34-36, are also ambiguous.

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## **COMMENTS/NOTES**

8. For clarity of independent claim 33, Applicant is respectfully requested to insert the structure of formula I into the claim.

- 9. For clarity of independent claim 1, Applicant is respectfully requested to identify the variables a-g.
- 10. It should be noted that no prior art has been cited against Applicant's claims. However, Applicant MUST address and overcome the double patenting and 112 rejections above. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious compounds and uses thereof as set forth in independent claims 1 and 33. The closest art is Applicant's own work which is cited in the double patenting rejection above.

#### **COMMENTS/NOTES**

- 11. Applicant is respectfully requested to provide the year of the documents listed on page 5 of information disclosure statement filed 5/10/04 in the next correspondence to the Examiner. Specifically, documents EG and EO need a year of publication.
- 12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. 3:15 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Johes

Primary Examiner

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February 18, 2005